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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,944	02/22/2006	Tadashi Yoneda	Q77281	8590

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EXAMINER	
GUPTA, ANISH	
ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
11/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/568,944	YONEDA, TADASHI	
	Examiner	Art Unit	
	ANISH GUPTA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of the species of a peptide of formula (I) wherein R is an isoalkyl group having 11 carbon atoms and X is a leucine in the reply filed on August 20, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

A search was conducted for the elected species. During the course of the search, prior art was found that disclosed the genus of claim 3. Accordingly, the all of the species taught in the prior art that read on the genus of claim 3 have been applied. The election of species IS NOT vacated however. This is because, while the prior art applied may disclose some members of the genus, the prior art does not dislose all of the members that belong the genus of "lipopeptide compound" as claimed in claim 1. Thus, the election of species is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yoneda et al. (WO99/62482) in view of Noda (JP07-304630) for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to cosmetic composition comprising a lipopeptide and a polyoxyethylene glyceryl ether fatty acid ester.

Yoneda et al. teaches cosmetic formulations comprising a lipopetide that has low skin penetration and low skin irritation (see abstract). Specifically, the reference disclose a lipopeptide having a sequence corresponding to Formula I as claimed in claim 3 (see page 5 and 6 of the reference). The reference states that the lipopeptide has a the effect of inhibiting the skin penetration of a skin irritating substance and reduces the irritation of a skin irritating substance such as a paraben compound (see page 6-7). The reference disclose the weight of the lipopeptide in an mount between .01 to 30% by weight (see page 7). The reference discloses that external cosmetic include skin milk, skin cream, foundation cream, massaging cream, cleansing cream, shaving cream, lotion, shampoo, hair tonic, hair dye (see page 14). The reference discloses a milky lotion that contains as one of the agents within the composition Avogado oil (see page 59). The difference between the prior art and the instant claims is that the reference does not specifically teach the use of polyoxyethylene glycerl fatty acid.

However, Noda et al. teach that conventional cosmetics contain oils require two steps of washing since the oil utilized in the makeup is not readily removed (see page 3 of translation). The reference states that this can be avoided if the cosmetic composition contains polyoxyethylene glyceryl fatty acid ester (see page 4 of translation). When this is used, not only does the composition

work as a cosmetic but also provides a foaming action that allows for the removal of the makeup in a single step fashion. The reference states that the composition containing the fatty acid ester has a high cleaning effect and has an excellent usability and feel (see page 10). The reference states that fatty acid ester can be either isostearic acid or oleic acid (See page 5). The composition can contain 1-80% of in the total weight of the composition (see page 5). The reference discloses that other agents can be added to the cosmetic such as polyhydric alcohol, propylene glycol, oil, paraffin, uv ray absorbent (see page 5). It would have been obvious, therefore, to use polyoxyethylene glycerly fatty acid ester in the cosmetic formulation of Yoneda because polyoxyethylene glyceryl fatty acid ester provides a composition that allows with a high cleaning effect and has an excellent usability and feel. The presence of polyoxyethylene glyceryl fatty removes the need to of a two step washing procedure to remove the makeup and avoid residual oil. There would have been reasonable expectation because Noda et al. teaches the presence of polyoxyethylene glyceryl fatty acid ester in cosmetic formulations such as lip stick, foundation, mascara etc. . . and Yoneda discloses the similar cosmetic formulations. Note that Yoneda discloses the presence of oil and wax in some of the cosmetic preparations. Thus, the claims are rendered obvious over the prior art.

With respect to the concentration ranges claimed, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See MPEP 2144.05. Here, the prior art disclose concentration ranges for the agent utilized. Thus, it would have been obvious to

optimize and improve upon what is already generally known to find the optimum combination of percentages.

Response to Arguments

Applicants argue that the "present invention provides the unexpected benefit of improving cosmetic washability, which is an important property for a cleansing cosmetic and a preservation of stability, by adding a specific amount of polyoxyethylene glyceryl ether fatty acid ester with a specific amount of lipopeptide compound." Applicants argue that the declaration submitted by Tadashi Yoneda demonstrates that balance between good washability and preservation stability cannot be achieved if polyoxyethylene sorbitan fatty acid ester is used in place of polyoxyethylene glyceryl ether fatty acid ester.

For Noda reference, Applicants argue that "although Noda suggests that polyoxyethylene glyceryl fatty acid ester is excellent in removing cosmetic, it does not provide a fresh feeling, which corresponds to the washability of the present invention."

Applicants arguments have been fully considered but have not been found persuasive.

First the Declaration provide by Applicants do not clearly establish unexpected results. The declaration states that Yoneda formulation separated into two layers and exhibited markedly poor preservation stability. Preservation was based solely on changes observed. However "observation" does not provide an object means of demonstrating stability. It is unclear how the separation of the Yoneda product implies or establishes poor preservation stability.

Secondly, the Declaration does not demonstrate why one would not expect separation to occur when the teachings of Noda are applied. That is the rejection is premised on modify the formulation of Yoneda with Noda. The Declaration does not clearly establish that one would have also expected a separation when Noda's teachings were applied to Yoneda.

With respect to Noda, Applicants argue Noda does not teach a fresh feeling. However, this is incorrect. Noda teaches when polyoxyethylene glyceryl fatty acid ester is used, not only does the composition work as a cosmetic but also provides a foaming action that allows for the removal of the makeup in a single step fashion. The reference states that the composition containing the fatty acid ester has a high cleaning effect and has an excellent usability and **feel** (see page 10). Thus, the reference disclose excellent feel. Applicants have not demonstrated where it is taught that the formulation did not result in a fresh feeling.

3. Claims 1-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. (JP2000136114) in view of Yoneda et al. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to cosmetic composition comprising a lipopeptide and a polyoxyethylene glyceryl ether fatty acid ester.

Saka et al. teaches cleansing cosmetic formulations that contain that drops the charge of face make up with high water resisting property (see page 2). The reference disclose formulations containg N-acyl glutamic acid diester as the active agent in the composition. The reference also states that in the cleansing formulation other agents such as bees wax, jojoba oil, non ionic surface agent such as polyoxyethylene fatty acid esters, and multivalent alcohol ester antiseptics can be used (see page 5). Specifically, the reference discloses a water-in-oil cleansing cream formulation that contains paraffin 40%wt, hydrogenated tallow 2 %wt, sorbitan sesquioleate 1.4 %, polyoxyethylene stearate 1.5 %, polyoxyethylene glyceryl isostearate 1.3 %, behenyl alc. 1 %, paraben 0.5 %, Eldew CL 202 (N-lauroylglutamic acid cholesteryl octyldodecyl ester) 5 %, 1,3-butanediol 3 %, glycerin 2.5

%, and H2O 41.8% (see abstract and example 1 on page 5). Note that the formulation contains polyoxyethylene glyceryl isostearate, which is the polyoxyethylene fatty acid ester and paraben. The difference between the prior art and the instant application is that the reference does not teach the use of a lipopeptide as claimed.

However, Yoneda et al. teaches cosmetic formulations comprising a lipopetide that has low skin penetration and low skin irritation (see abstract). Specifically, the reference disclose a lipopeptide having a sequence corresponding to Formula I as claimed in claim 3 (see page 5 and 6 of the reference). The reference states that the lipopeptide has a the effect of inhibiting the skin penetration of a skin irritating substance and reduces the irritation of a skin irritating substance such as a paraben compound (see page 6-7). The reference disclose the weight of the lipopeptide in an mount between .01 to 30% by weight (see page 7). The reference discloses that external cosmetic include skin milk, skin cream, foundation cream, massaging cream, cleansing cream, shaving cream, lotion, shampoo, hair tonic, hair dye (see page 14). It would have been obvious, therefore, to formulate the composition of Sakai et al. with the lipopeptide of Yoneda because the presence of lipopeptide has a the effect of inhibiting the skin penetration of a skin irritating substance and reduces the irritation of a skin irritating substance such as a paraben compound. Note that Sakai et al. teaches a specific formulation with paraben. There would have been a reasonable expectation of success because Yoneda et al. teaches that the lipopeptide can be formulated into cosmetic cleaning compositions. Thus, the claims are rendered obvious.

With respect to the concentration ranges claimed, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See MPEP 2144.05. Here, the prior art disclose concentration ranges for the agent utilized. Thus, it would have been obvious to optimize and improve upon what is already generally known to find the optimum combination of percentages.

Response to Arguments

Applicants raise similar arguments for Yoneda as above and these arguments have been discussed supra.

Applicants also argue Sakai's polyoyethylene glyceryl ether fatty acid ester is different than that form the claimed invention and shows polyoxyethylene fatty acid ester only as an example of nonionic surfactant which has been conventionally used in cosmetics, and only as an optional ingredient.

Applicants arguments have been fully considered but have not been found persuasive.

It is unclear what Applicants seem to be arguing. The claims recite polyoxyethylene glyceryl ether fatty acid ester. Sakai et al. teaches a formulation that contains non ionic surface agent such as polyoxyethylene fatty acid esters. The reference specifically teaches a formulation that contains polyoxyethylene glyceryl isostearate at 1.3 % of the formulation. This meets the claimed limitation. The mere fact that the reference teaches it as an optional ingredient does not limit the teachings of the reference. Based on the Sakai disclosure, one can make a water-in-oil cleansing cream formulation that contains paraffin 40%wt, hydrogenated tallow 2 %wt, sorbitan sesquioleate 1.4 %, polyoxyethylene stearate 1.5 %, polyoxyethylene glyceryl isostearate 1.3 %, behenyl alc. 1 %, paraben 0.5 %, Eldew CL 202 (N-lauroylglutamic acid cholesteryl octyldodecyl ester) 5 %, 1,3-butanediol 3

%, glycerin 2.5 %, and H2O 41.8% (see abstract and example 1 on page 5). One would be motivated to add lipopeptide to this formulation because the presence of lipopeptide has a the effect of inhibiting the skin penetration of a skin irritating substance and reduces the irritation of a skin irritating substance such as a paraben compound.

Rejection is maintained.

4. Claims 1-6, 8, 10, 12 and 14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (JP09-165320) in view of Yoneda et al. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to cosmetic composition comprising a lipopeptide and a polyoxyethylene glyceryl ether fatty acid ester.

Saka et al. teaches cleansing cosmetic formulation in the form of a hair rinse agent composition which has a high rinsing effect and excellent in feel (see abstract). Specifically, the reference discloses a composition that contains lauryltrimethylammonium chloride, stearyltrimethylammonium chloride, cetanol, polyoxyethylene sorbitan tetraoleate, sorbitan monooleate, glycerin monocaprylate, liq. paraffin, perfume, and paraben (see abstract and pages 7-8). Note that the formulation contains polyoxyethylene sorbitan tetroleate, which is the polyoxyethylene sorbit fatty acid ester and paraben. The reference exemplifies formulation where the concentration of the fatty acid ester is 2.5% by weight (see page 7). The difference between the prior art and the instant application is that the reference does not teach the use of a lipopeptide as claimed.

However, Yoneda et al. teaches cosmetic formulations comprising a lipopetide that has low skin penetration and low skin irritation (see abstract). Specifically, the reference disclose a lipopeptide having a sequence corresponding to Formula I as claimed in claim 3 (see page 5 and 6 of

the reference). The reference states that the lipopeptide has a the effect of inhibiting the skin penetration of a skin irritating substance and reduces the irritation of a skin irritating substance such as a paraben compound (see page 6-7). The reference disclose the weight of the lipopeptide in an mount between .01 to 30% by weight (see page 7). The reference discloses that external cosmetic include skin milk, skin cream, foundation cream, massaging cream, cleansing cream, shaving cream, lotion, shampoo, hair tonic, hair dye (see page 14). It would have been obvious, therefore, to formulate the composition of Sakai et al. with the lipopeptide of Yoneda because the presence of lipopeptide has a the effect of inhibiting the skin penetration of a skin irritating substance and reduces the irritation of a skin irritating substance such as a paraben compound. Note that Ito et al. teaches a specific formulation with paraben. There would have been a reasonable expectation of success because Yoneda et al. teaches that the lipopeptide can be formulated into shampoos and hair tonic compositions. Thus, the claims are rendered obvious.

With respect to the concentration ranges claimed, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See MPEP 2144.05. Here, the prior art disclose concentration ranges for the agent utilized. Thus, it would have been obvious to optimize and improve upon what is already generally known to find the optimum combination of percentages.

Response to Arguments

Applicants argue that Ito does not does not describe the use of or the unexpected benefits of the claimed composition.

Applicants arguments have been fully considered but have not been found persuasive.

The Declaration provide by Applicants do not clearly establish unexpected results. The declaration states that Yoneda formulation separated into two layers and exhibited markedly poor preservation stability. Preservation was based solely on changes observed. However "observation" does not provide an object means of demonstrating stability. It is unclear how the separation of the Yoneda product implies or establishes poor preservation stability.

Secondly, the Declaration does not demonstrate why one would not expect separation to occur when the teachings of Yoneda are applied to Ito. The Declaration does not clearly establish that one would have also expected a separation from the Ito formulation. Thus, the Declaration does not provide any means of measure for unexpected results when compared to Ito.

The rejection is maintained.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/
Primary Examiner, Art Unit 1654